

7-05
5 October 2005

FIRST REVIEW REPORT

APPLICATION A543

**FOOD DERIVED FROM INSECT-PROTECTED,
GLUFOSINATE AMMONIUM-TOLERANT CORN
LINE 59122-7**

1. Introduction

On 15 September 2005, the Australia and New Zealand Food Regulation Ministerial Council requested a first Review of Application A543, which seeks approval of food derived from insect-protect, glufosinate ammonium-tolerant corn line DAS-59122-7. Approval of this Application involves a variation to Standard 1.5.2 – Food Produced by Gene Technology, of the *Australia New Zealand Food Standards Code* (the Code).

Following a request for a formal review, FSANZ has 3 months to prepare a response, in this instance, FSANZ is required to review the decision by 15 December 2005.

2. Objectives of Review

The objective of this Review is to reconsider the draft variation to Standard 1.5.2 in light of the Ministerial Council's concerns as outlined in Section 3.

3. Grounds for the review requested by the Ministerial Council

The First Review was requested on the grounds that Application A543 'does not protect public health and safety' and 'does not provide adequate information to enable informed choice'. No specific reasons were given.

4. Issues addressed in First Review

The issues raised by the Ministerial Council in this First Review have been addressed by the measures adopted at Final Assessment, which were re-affirmed at First Review, these are summarised in the following table:

Ministerial Council issue	Measures taken at Final Assessment	Additional measures at First Review
<ul style="list-style-type: none">• Protection of public health and safety	<ul style="list-style-type: none">• FSANZ carried out a full safety assessment and was satisfied that corn line DAS59122-7 was safe for human consumption, and is not a public health and safety concern.• As for all GM applications, FSANZ called for two rounds of public comments; there were no specific concerns with the public health and safety of corn line DAS59122-7.	FSANZ reviewed the safety assessment report of A543 and concluded that all the criteria requested in FSANZ's Guidelines for GM Applications had been satisfied and that no further data was required.
<ul style="list-style-type: none">• Inadequate information to enable informed choice	<ul style="list-style-type: none">• Labelling of GM foods provides information to enable informed choice. Under the labelling regulations of GM foods in Standard 1.5.2, if novel DNA and/or protein were found in the final food then labelling would be required. Labelling will be required for some products derived from corn line DAS59122-7.	FSANZ re-affirms that labelling will be required for some products from this corn. However, if food products are processed such that no novel DNA and/or protein is present in the final food, labelling will not be required.

5. Review Options

There are three options proposed for consideration under this Review:

1. re-affirm approval of the draft variation to Standard 1.5.2 of the Code as notified to the Council; or
2. re-affirm approval of the draft variation to Standard 1.5.2 of the Code subject to any amendments FSANZ considers necessary; or
3. withdraw approval of the draft variation to Standard 1.5.2 of the Code as notified to the Council.

No additional data has been presented to the Board to justify consideration of Options 2 and 3.

The recommended option is Option 1.

6. The Decision

FSANZ gives approval for the use and sale of food derived from corn line DAS59122-7. This re-affirms the approval of the draft variation to Standard 1.5.2 of the Code to give effect to this decision.

6.1 Statement of Reasons

An amendment to Standard 1.5.2 to give approval to the sale and use of food derived from corn line DAS59122-7 in Australia and New Zealand is agreed on the basis of the available scientific evidence for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the use of corn line DAS59122-7;
- FSANZ considers that food derived from corn line DAS59122-7 is equivalent to food from other commercially available corn varieties in terms of its safety for human consumption and nutritional adequacy;
- a regulation impact assessment process has been undertaken that also fulfils the requirement in New Zealand for an assessment of compliance costs. The assessment concluded that the amendment to Standard 1.5.2 is of net benefit to both food producers and consumers; and
- the proposed draft variation to Standard 1.5.2 is consistent with the section 10 objectives of the Act, the regulatory impact assessment and requirements of Standard 1.5.2. The proposed draft variation is provided in **Attachment 1**.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*.
2. Summary and Conclusions from the Final Assessment Report

Attachment 1

DRAFT VARIATION TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: On gazettal

[1] *Standard 1.5.2 of the Australia New Zealand Food Standards Code is varied by inserting into Column 1 of the Table to clause 2 –*

Food derived from insect-protected, glufosinate ammonium-tolerant corn line DAS-59122-7

SUMMARY AND CONCLUSIONS OF THE SAFETY ASSESSMENT OF FOOD DERIVED FROM CORN LINE DAS59122-7

Background

Food derived from genetically modified (GM) corn line DAS-59122-7 has been assessed for its safety for human consumption. This corn line has been genetically modified to be resistant to insect attack and herbicide tolerant and has been developed for cultivation in North America. Therefore, if approved, food derived from corn line DAS-59122-7 may enter the Australian and New Zealand food supply as imported food products.

A number of criteria have been addressed in the safety assessment including: a characterisation of the transferred genes, their origin, function and stability; changes at the DNA, protein and whole food levels; compositional analyses; evaluation of intended and unintended changes; and the potential for the newly expressed proteins to be either allergenic or toxic to humans.

History of Use

Corn (*Zea mays L*), otherwise known as maize, is the world's third leading cereal crop, behind wheat and rice, and is grown in over 25 countries worldwide. Corn-derived products are routinely used in a large number and diverse range of foods and have a long history of safe use. Products derived from DAS-59122-7 corn may include flour, breakfast cereals, high fructose corn syrup and other starch products.

Description of the Genetic Modification

Corn line DAS-59122-7 contains two novel genes, *cry34Ab1* and *cry35Ab1*, encoding the insecticidal proteins Cry34Ab1 and Cry35Ab1. These two genes were derived from the soil bacterium *Bacillus thuringiensis* and are selectively toxic to certain insect pests of corn. Corn line DAS-59122-7 also contains a copy of the *pat* gene, encoding the enzyme phosphinothricin acetyl transferase (PAT), which confers tolerance to the herbicide glufosinate ammonium.

Detailed molecular and genetic analyses of corn line DAS-59122-7 indicate that the transferred *cry34Ab1*, *cry35Ab1* and *pat* genes are stably integrated into the plant genome at one insertion site and are stably inherited from one generation to the next.

Characterisation of Novel Protein

Corn line DAS-59122-7 expresses three novel proteins – Cry34Ab1, Cry35Ab1, and PAT. In the corn grain, the PAT protein is undetectable. Cry34Ab1 is expressed at levels ranging from 28.9-117 ng/mg dry weight in DAS-59122-7 corn grain and Cry35Ab1 at levels ranging from not detectable to 1.83 ng/mg.

Acute oral toxicity studies have been conducted on the Cry34Ab1, Cry35Ab1, and PAT proteins – there was no evidence of toxicity in all cases. Potential allergenicity was assessed by sequence comparison to known allergens, simulated digestion studies and by determining thermolability – these data did not indicate any potential for allergenicity.

Comparative Analyses

Compositional analyses were done to establish the nutritional adequacy of grain from corn line DAS-59122-7, and to compare it to a non-transgenic control line and commercial varieties of corn. The constituents measured were protein, fat, carbohydrate, ash, moisture, fibre, fatty acids, amino acids, vitamins, minerals, secondary metabolites and anti-nutrients.

No differences of biological significance were observed between the transgenic corn grain and its non-GM counterpart. Several minor differences in key nutrients and other constituents were noted however the levels observed represented very small differences and do not indicate an overall pattern of change that would warrant further investigation. On the whole, it was concluded that food from corn line DAS-59122-7 is equivalent in composition to that from other commercial corn varieties.

Nutritional Impact

The detailed compositional studies are considered adequate to establish the nutritional adequacy of the food and indicate that food derived from corn line DAS-59122-7 is equivalent in composition to food from non-GM corn varieties. The introduction of food produced from corn line DAS-59122-7 into the food supply is therefore expected to have minimal nutritional impact.

Conclusion

No potential public health and safety concerns have been identified in the assessment of food produced from corn line DAS-59122-7. On the basis of the data provided in the present application, and other available information, food produced from corn line DAS-59122-7 can be considered as safe and as wholesome as food produced from other corn varieties.